

Application of: Martin, Howard

Serial No.:10/821,693

REMARKS

This amendment is submitted in response to the Office Action dated 13 December 2005, the time to respond being until 13 March 2005. Claims 1, 3, 5, 7, 10-12 and 15 are amended, and claims 2, 4, 6, 9, 13-14 and 16 are canceled. Thus, claims 1, 3, 5, 7-8, 10-12 and 15 remain pending in this application.

The Examiner rejected Applicant's claim for the benefit of the prior-filed provisional application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) because the present application is indicated as having been filed on 10 April 2004, outside one year. Applicant contends that the present application was filed on Friday April 8, 2005 and not Sunday April 10, 2005 as shown by the Patent Office records. Applicant submits herewith the USPS tracking record for the subject mailing which shows that the Express Mail package was received at the USPS distribution facility at BWI Airport on April 9, 2005. This was a Saturday, and Applicant's offices in downtown Baltimore were closed. Clearly, as shown on Applicant's transmittal letter, the Express Mail envelope was deposited in downtown Baltimore on Friday April 8, 2005, and was routed through the BWI facility on Saturday. Applicant requests acceptance of its priority claims inasmuch as the present application was filed on Friday April 8, 2005.

The Examiner objected to claim 10 as being dependent on itself and to claim 13 for depending on claim 1 rather than the intended claim 12. Applicant appreciates the Examiner's notations and has amended the dependencies accordingly.

Application of: Martin, Howard

Serial No.:10/821,693

The Examiner rejected claims 6-8 under 35 U.S.C. 112, second paragraph, because the preamble "further comprises" in claim 6 implies there are additional structural elements, Claim 6 is herein canceled.

The Examiner further rejected claims 1, 2, 4, 6, and 9 under 35 U.S.C. 102(b) as being anticipated by Chadwick et al. (WO 01/41668 A1). According to the Examiner, Chadwick et al. discloses each and every recited element of claim 1. First of all, Applicant acknowledges and appreciates the time taken by the Examiner during the March 7 telephone interview which served greatly to clarify the Examiner's stance. While Chadwick does disclose a combination mirror and gauge for setting the lengths of *dental cutting tools*, it is a three piece device. The handle (13) incorporates a well or socket (48) which includes a threaded sleeve (18) (see FIG. 3) which engages a threaded rod (14). The length or depth of the well or socket (48) can be adjusted by rotating the sleeve (18) until the well (48) is set at a desired depth. The sleeve is then locked by a threaded ring (16). A dental tool (50) then inserted into the well (48) can be set to a predetermined depth of operation with a depth stop (54) (FIG. 2) on the tool (50) adjusted to set this depth. This design requires intricately machined components (threaded sleeve 18 and rod 30) which require lubrication, are much more difficult to sterilize, and can act as a catchment for debris, blood, necrotic-infected tissue, etc. This can lead to infection.¹ Moreover, the three-piece

¹ The Chadwick design would require a three step cleaning, disinfection sterilization process to eliminate infectious debris from the internal threads, locking mechanism and capping design. These steps are hand cleaning, followed by ultrasonic cleaning to eliminate debris and material from the grooves, serrations, locks, internal opening cylinder, etc and thence to autoclaving.

Application of: Martin, Howard

Serial No.:10/821,693

design is much more complicated in use when compared to the present invention because of the multiple adjustments involved. Working ease of usage is mandatory in a dental setting, and all instruments must be lightweight and facile to work with. Indeed, it is essential that such instruments be usable at chairside with one hand. Chadwick simply does not meet these requirements as it requires insertion of the instrument, followed by two-handed manipulation the sleeve (18), and two-handed screwing the locking ring (16) into place. Next, the instrument (e.g., root canal file) must be inserted into the cylindrical hole within the handle of the Chadwick instrument necessitating a precise guidance. A dentist can easily miss and jab himself with a contaminated pointed file. This is analogous to the highly publicized problem of recapping needles after injection. Furthermore, the Chadwick design must be readjusted for each new instrument to be used. The present invention is specifically designed to avoid the foregoing problems entirely, and claim 1 is herein amended to more clearly recite the structural differences that do this. Specifically, claim 1 now recites "a dental mirror integrally attached to the operative first end of said handle shaft", and "a measuring device comprising "a channel formed integrally in the second end of the handle shaft and *defined by an open-faced groove having a semi-circular cross-section adapted to conform to and receive an existing root canal file inserted lengthwise therein, said groove opening distally into the second end of said shaft and extending open-faced from the second end along a length of said handle*, and measuring lines equally-spaced along said shaft proximate said channel for demarcating an extent of said channel relative to said second end." A functional clause is also added to explain that the open-faced groove *positions*

Application of: Martin, Howard

Serial No.:10/821,693

and secures said file therein, and said measuring lines provide a visual indication of an extent to which a root canal file is inserted therein.” It is believed that these changes structurally as well as functionally distinguish claim 1 from Chadwick et al.. The one-piece construction (rather than three piece with adjustable handle) allows more easy insertion of a file and length-adjustment single-handedly. Moreover, as stated in claim 11 the entire configuration can be formed of an autoclavable and chemoclavable material and the risk of infection is greatly reduced. The present design is easily hand cleaned, followed by either chemical or autoclaving sterilization. There are no grooves, locking mechanisms, threads or serration, or clips to harbor debris. This is significant since the World Health Organization, CDC, and OSAP (Organization for Sterilization and Asepsis Procedures-Dental) has requested that all instruments attempt to meet a standard of ease of infection control. Chadwick does not meet this requirement, whereas the present design does. Consequently, claim 1 is patentably distinguished. Note that Petty ‘522 (cited and further distinguished below) merely shows a flat ruler which, when take in combination with Chadwick, still fails to teach or suggest the structural limitations of the above-described channel as claimed.

All of claims 2, 4, 6, and 9 are canceled.

The Examiner also rejected Claim 3 under 35 U.S.C. 103(a) as being unpatentable over Chadwick et al. in view of Petty et al. (U.S. 4,252,522). According to the Examiner, Chadwick et al. disclose the combination dental mirror and measuring gauge described earlier but not the particular incrementing of the indices in scale. The Examiner contends that it is well known in the art and a matter of common sense to increment such scales in millimeters and to mark major

Application of: Martin, Howard

Serial No.:10/821,693

intervals at some larger increment, such as 5 mm, in order to improve visual approximation, and such is demonstrated Petty et al (Fig. 2). While this may be true for measuring in general, it is not so apparent in the content of the present device, which is specifically adapted (vis a vis semi-circular groove running along the side of the shaft for a distance of approximately thirty millimeters from the flat end) for a particular method of measurement described in the specification as placing a root canal file with an attached rubber stopper (indicating the depth of the apical foramen) within the groove such that the rubber stopper abutting the flat end of the shaft. The length of the file from the flat end of the shaft to its end point within the groove can easily be measured by observing the provided markings. To establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant." Also, it is well settled that an inventive combination cannot be anticipated by finding individual features separately in the prior art and combining them in a piecemeal manner to show obviousness. See *In re Kamm and Young*, 17 USPQ 298, *affd.* (Court held that "The rejection here runs afoul of a basic mandate inherent in section 103 - that a piecemeal reconstruction of the prior art patents in the light of appellants disclosure shall not be the basis for a holding of obviousness.) Neither reference disclose a suggestion/motivation to combine, nor has the Examiner indicated a suggestion/motivation to combine the references. Because the Examiner is improperly piecing together features found in separate prior art references, the combination is improper, and thus the Examiner has failed to make a *prima facie* case of obviousness. Therefore,

Application of: Martin, Howard

Serial No.:10/821,693

claim3 is patentably distinguished on its own merits, and because it depends from claim 1 and incorporates those patentable limitations.

Claim 5 was rejected under 35 U.S.C. 103(a) as being unpatentable over Chadwick in view of Frider et al. (U.S. 6,932,601). According to the Examiner, Chadwick et al. disclose all elements of claim 5 except for the angled mirror of particular dimensions. While Applicant concedes that the present mirror is the well-known contra style, Chadwick et al. does not teach or suggest the inherent elements of claim 1 as explained above.

Claims 7, 12, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chadwick et al. in view of Forrest et al. (U.S. 3,911,587). According to the Examiner, Forrest et al. add the appropriate length for root canal penetration of 30 mm max. While this may be true in respect to claim 7, it is inapposite in regard to claim 12. Like claim 1, claim 12 is herein amended to distinguish Chadwick based on the fundamental distinction of adjusting the file within the integrally-formed shaft (versus adjusting a three-part sleeve/rod/lock nut to accommodate the file as in the threaded-sleeve configuration of Chadwick), and Forrest et al. fails to bridge this gap. Moreover, claim 12 now recites the "*open-faced* channel, for receiving a portion of a root canal file, running approximately thirty millimeters along its length and opening to one end of said shaft, said open-faced channel having a width, depth, and cross-section adapted to conform to and seat said root canal file when inserted lengthwise therein, and to allow for said root canal file to freely slide along the length of the channel. Thus, claim 12 as amended is patentably distinguished for all the same above-described reasons in regard to claim 1, and

Application of: Martin, Howard

Serial No.:10/821,693

claim 7 depends from claim 1 and is likewise distinguished. Claims 13 and 14 are canceled.

Claims 8 and 10 were rejected under 35 U.S.C. 103(a) as being unpatentable over Chadwick et al. in view of Johnsen et al. (U.S. 6,036,490) and Vice (U.S. 4,028,810). According to the Examiner, Chadwick et al. discloses all elements of claims 8 and 10 except for the shape of the groove and dimensions of either the groove or channel. Vice suggests a dimension for his own device between 0.75 and 1.0 mm, but this in no way teaches how to adapt the present device. Applicant admitted that his groove conforms to and receive a conventional root canal file, but the dimensions of the root canal file do not dictate the existence, shape or dimensions of the present channel. This again is hindsight piecemeal reconstruction of applicant's device.

Claim 11 was rejected under 35 U.S.C. 103(a) as being unpatentable over Chadwick et al. in view of Berk et al. (U.S. 6,595,775). According to the Examiner, Berk et al. (column 4, lines 38-40) suggest the materials of construction. However, claim 11 is herein amended to specify that applicants entire device is integrally formed of said materials, which is the real key to sterilization and to avoid infection (as described above). This distinguishes the three-piece construction of Chadwick (Berk adds nothing in this regard), and so claim 11 is patentably distinguished.

Claim 15 was rejected under 35 U.S.C. 103(a) as being unpatentable over Chadwick et al. in view of Vice as applied to claims 8 and 10 above, and further in view of Forrest et al. However, claim 15 incorporates the same patentable limitations of claim 12 and is likewise distinguished.

Application of: Martin, Howard

Serial No.:10/821,693

In view of the above, all pending claims 1, 3, 5, 7-8, 10-12 and 15 are believed to avoid all the objections/rejections set forth in the Official Action and thus, the case should be in condition for allowance. A Notice to this effect is respectfully requested, and the Examiner is invited to call the undersigned at 410.385.2383 to discuss any remaining issues.

Application of: Martin, Howard

Serial No.:10/821,693

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Respectfully submitted,

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